

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION**

GILEAD SCIENCES, INC. and
EMORY UNIVERSITY,

Plaintiffs,

v.

MYLAN INC. and MYLAN
PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 1:14-cv-99 (IMK)

**PLAINTIFFS' ANSWER TO DEFENDANT MYLAN PHARMACEUTICALS INC.'S
AMENDED COUNTERCLAIMS**

Plaintiffs-Counterclaim Defendants Gilead Sciences, Inc. ("Gilead") and Emory University ("Emory") (collectively, "Plaintiffs") answer the amended counterclaims of Defendant-Counterclaim Plaintiff Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") as follows:

PARTIES

1. Plaintiffs admit that Gilead is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 333 Lakeside Drive, Foster City, California 94404.

2. Plaintiffs admit that Emory is a non-profit corporation organized and existing under the laws of Georgia with its corporate headquarters at 201 Dowman Drive, Atlanta, Georgia 30322.

3. On information and belief, Plaintiffs admit that Mylan Pharmaceuticals is a corporation organized under the laws of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

JURISDICTION AND VENUE

4. Paragraph 4 of Mylan Pharmaceuticals's amended counterclaims contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Plaintiffs admit that Mylan Pharmaceuticals purports to assert counterclaims under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Plaintiffs deny all remaining allegations of Paragraph 4 of Mylan Pharmaceuticals's amended counterclaims.

5. Paragraph 5 of Mylan Pharmaceuticals's amended counterclaims contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Plaintiffs admit that the Court has subject matter jurisdiction over Mylan Pharmaceuticals's amended counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a). Plaintiffs deny all remaining allegations of Paragraph 5 of Mylan Pharmaceuticals's amended counterclaims.

6. Paragraph 6 of Mylan Pharmaceuticals's amended counterclaims contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Plaintiffs admit that the Court has personal jurisdiction over Plaintiffs for purposes of these amended counterclaims. Plaintiffs deny all remaining allegations of Paragraph 6 of Mylan Pharmaceuticals's amended counterclaims.

7. Paragraph 7 of Mylan Pharmaceuticals's amended counterclaims contains legal conclusions and allegations to which no answer is required. To the extent that an answer is

required, Plaintiffs admit that venue for Mylan Pharmaceuticals's amended counterclaims is proper in this District. Plaintiffs deny all remaining allegations of Paragraph 7 of Mylan Pharmaceuticals's amended counterclaims.

PATENTS-IN-SUIT

8. Plaintiffs admit that, on November 4, 2003, the United States Patent and Trademark Office ("USPTO") issued United States Patent No. 6,642,245 (the "'245 patent"), entitled "Antiviral Activity and Resolution of 2-Hydroxymethyl-5-(5-Fluorocytosin-1-yl)-1,3-Oxathiolane." Plaintiffs further admit that Emory is the owner of the '245 patent and, pursuant to an agreement entered into between Gilead and Emory, Gilead has an exclusive license under the '245 patent, including but not limited to the right to sue for infringement of the '245 patent.

9. Plaintiffs admit that, on March 9, 2004, the USPTO issued United States Patent No. 6,703,396 (the "'396 patent"), entitled "Method of Resolution and Antiviral Activity of 1,3-Oxathiolane Nucleoside Enantiomers." Plaintiffs further admit that Emory is the owner of the '396 patent and, pursuant to an agreement entered into between Gilead and Emory, Gilead has an exclusive license under the '396 patent, including but not limited to the right to sue for infringement of the '396 patent.

10. Plaintiffs admit that, on November 26, 2013, the USPTO issued United States Patent No. 8,592,397 (the "'397 patent"), entitled "Compositions and Methods for Combination Antiviral Therapy." Plaintiffs further admit that Gilead is the assignee of the '397 patent.

11. Plaintiffs admit that, on May 6, 2014, the USPTO issued United States Patent No. 8,716,264 (the "'264 patent"), entitled "Compositions and Methods for Combination Antiviral Therapy." Plaintiffs further admit that Gilead is the assignee of the '264 patent.

12. Plaintiffs admit that Gilead is indicated in the records of the United States Food and Drug Administration as the holder of New Drug Application No. 21-752 for 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate, which are prescribed and sold by Gilead under the Truvada® trademark.

13. Plaintiffs admit that the '245, '396, '397, and '264 patents are listed in the electronic version of the Orange Book in association with Truvada®.

14. Paragraph 14 of Mylan Pharmaceuticals's amended counterclaims contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Plaintiffs admit that Mylan Pharmaceuticals notified Plaintiffs in writing by a letter dated April 24, 2014 (the "April 24, 2014 Notice Letter") that it had filed Abbreviated New Drug Application ("ANDA") No. 20-6436 with a certification provided for in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '245, '396, and '397 patents are invalid, unenforceable, and/or will not be infringed by the product that is the subject of ANDA No. 20-6436. Plaintiffs deny that the '245, '396, and '397 patents are invalid, unenforceable, and/or will not be infringed by the product that is the subject of ANDA No. 20-6436. Plaintiffs further deny all remaining allegations in Paragraph 14.

15. Paragraph 15 of Mylan Pharmaceuticals's amended counterclaims contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Plaintiffs deny that the April 24, 2014 Notice Letter included a full and detailed statement of the factual and legal basis for the certification that the '245, '396, and '397 patents are invalid, unenforceable, and/or will not be infringed by the product that is the subject of ANDA No. 20-6436. Plaintiffs further deny that the '245, '396, and '397 patents are invalid,

unenforceable, and/or will not be infringed by the product that is the subject of ANDA No. 20-6436. Plaintiffs further deny all remaining allegations in Paragraph 15.

16. Paragraph 16 of Mylan Pharmaceuticals's amended counterclaims contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Plaintiffs admit that Mylan Pharmaceuticals notified Plaintiffs in writing by a letter dated December 12, 2014 (the "December 12, 2014 Notice Letter") that it had filed ANDA No. 20-6436 with a certification provided for in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '264 patent is invalid, unenforceable, and/or will not be infringed by the product that is the subject of ANDA No. 20-6436. Plaintiffs deny that the '264 patent is invalid, unenforceable, and/or will not be infringed by the product that is the subject of ANDA No. 20-6436. Plaintiffs further deny all remaining allegations in Paragraph 16.

17. Paragraph 17 of Mylan Pharmaceuticals's amended counterclaims contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Plaintiffs deny that the December 12, 2014 Notice Letter included a full and detailed statement of the factual and legal basis for the certification that the '264 patent is invalid, unenforceable, and/or will not be infringed by the product that is the subject of ANDA No. 20-6436. Plaintiffs further deny that the '264 patent is invalid, unenforceable, and/or will not be infringed by the product that is the subject of ANDA No. 20-6436. Plaintiffs further deny all remaining allegations in Paragraph 17.

18. Plaintiffs admit that, on June 9, 2014, they filed a Complaint in this Court against Mylan Inc. and Mylan Pharmaceuticals alleging infringement of the '245, '396, and '397 patents. Plaintiffs further admit that, on June 27, 2014, they filed an Amended Complaint in this action, again alleging infringement of the '245, '396, and '397 patents. Plaintiffs further admit that, on

January 22, 2015, they filed a Second Amended Complaint in this action, alleging infringement of the '245, '396, '397, and '264 patents.

FIRST CLAIM FOR RELIEF
(Declaratory Judgment of Non-Infringement of the '245 Patent)

19. Plaintiffs repeat their answers to Paragraphs 1-18, as if fully stated herein.
20. Plaintiffs admit that they have accused Mylan Pharmaceuticals of infringing the '245 patent.
21. Plaintiffs deny the allegations in Paragraph 21.
22. Plaintiffs admit that a definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Mylan Pharmaceuticals and Plaintiffs regarding the infringement of the '245 patent.
23. Plaintiffs deny the allegations in Paragraph 23.

SECOND CLAIM FOR RELIEF
(Declaratory Judgment of Non-Infringement of the '396 Patent)

24. Plaintiffs repeat their answers to Paragraphs 1-23, as if fully stated herein.
25. Plaintiffs admit that they have accused Mylan Pharmaceuticals of infringing the '396 patent.
26. Plaintiffs deny the allegations in Paragraph 26.
27. Plaintiffs admit that a definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Mylan Pharmaceuticals and Plaintiffs regarding the infringement of the '396 patent.
28. Plaintiffs deny the allegations in Paragraph 28.

THIRD CLAIM FOR RELIEF
(Declaratory Judgment of Non-Infringement of the '397 Patent)

29. Plaintiffs repeat their answers to Paragraphs 1-28, as if fully stated herein.

30. Plaintiffs admit that they have accused Mylan Pharmaceuticals of infringing the '397 patent.

31. Plaintiffs deny the allegations in Paragraph 31.

32. Plaintiffs admit that a definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Mylan Pharmaceuticals and Plaintiffs regarding the infringement of the '397 patent.

33. Plaintiffs deny the allegations in Paragraph 33.

FOURTH CLAIM FOR RELIEF
(Declaratory Judgment of Non-Infringement of the '264 Patent)

34. Plaintiffs repeat their answers to Paragraphs 1-33, as if fully stated herein.

35. Plaintiffs admit that they have accused Mylan Pharmaceuticals of infringing the '264 patent.

36. Plaintiffs deny the allegations in Paragraph 36.

37. Plaintiffs admit that a definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Mylan Pharmaceuticals and Plaintiffs regarding the infringement of the '264 patent.

38. Plaintiffs deny the allegations in Paragraph 38.

FIFTH CLAIM FOR RELIEF
(Declaratory Judgment of Invalidity of the '245 Patent)

39. Plaintiffs repeat their answers to Paragraphs 1-38, as if fully stated herein.

40. Plaintiffs admit that they have accused Mylan Pharmaceuticals of infringing the '245 patent.

41. Plaintiffs deny the allegations in Paragraph 41.

42. Plaintiffs deny the allegations in Paragraph 42.

43. Plaintiffs deny the allegations in Paragraph 43.

44. Plaintiffs admit that there is a definite and concrete, real and substantial, justiciable, and continuing case or controversy between Mylan Pharmaceuticals and Plaintiffs regarding the infringement and validity of the '245 patent. Plaintiffs deny that this case or controversy warrants the issuance of a declaratory judgment.

45. Plaintiffs deny the allegations in Paragraph 45.

SIXTH CLAIM FOR RELIEF
(Declaratory Judgment of Invalidity of the '396 Patent)

46. Plaintiffs repeat their answers to Paragraphs 1-45, as if fully stated herein.

47. Plaintiffs admit that they have accused Mylan Pharmaceuticals of infringing the '396 patent.

48. Plaintiffs deny the allegations in Paragraph 48.

49. Plaintiffs deny the allegations in Paragraph 49.

50. Plaintiffs deny the allegations in Paragraph 50.

51. Plaintiffs admit that there is a definite and concrete, real and substantial, justiciable, and continuing case or controversy between Mylan Pharmaceuticals and Plaintiffs regarding the infringement and validity of the '396 patent. Plaintiffs deny that this case or controversy warrants the issuance of a declaratory judgment.

52. Plaintiffs deny the allegations in Paragraph 52.

SEVENTH CLAIM FOR RELIEF
(Declaratory Judgment of Invalidity of the '397 Patent)

53. Plaintiffs repeat their answers to Paragraphs 1-52, as if fully stated herein.

54. Plaintiffs admit that they have accused Mylan Pharmaceuticals of infringing the '397 patent.

55. Plaintiffs deny the allegations in Paragraph 55.

56. Plaintiffs deny the allegations in Paragraph 56.

57. Plaintiffs deny the allegations in Paragraph 57.

58. Plaintiffs admit that there is a definite and concrete, real and substantial, justiciable, and continuing case or controversy between Mylan Pharmaceuticals and Plaintiffs regarding the infringement and validity of the '397 patent. Plaintiffs deny that this case or controversy warrants the issuance of a declaratory judgment.

59. Plaintiffs deny the allegations in Paragraph 59.

EIGHTH CLAIM FOR RELIEF
(Declaratory Judgment of Invalidity of the '264 Patent)

60. Plaintiffs repeat their answers to Paragraphs 1-59, as if fully stated herein.

61. Plaintiffs admit that they have accused Mylan Pharmaceuticals of infringing the '264 patent.

62. Plaintiffs deny the allegations in Paragraph 62.

63. Plaintiffs deny the allegations in Paragraph 63.

64. Plaintiffs deny the allegations in Paragraph 64.

65. Plaintiffs admit that there is a definite and concrete, real and substantial, justiciable, and continuing case or controversy between Mylan Pharmaceuticals and Plaintiffs regarding the infringement and validity of the '264 patent. Plaintiffs deny that this case or controversy warrants the issuance of a declaratory judgment.

66. Plaintiffs deny the allegations in Paragraph 66.

PRAYER FOR RELIEF

The “WHEREFORE” paragraph following Paragraph 66 of Mylan Pharmaceuticals’s amended counterclaims that states Mylan Pharmaceuticals’s prayer for relief, including sub-paragraphs (a)-(g), does not require an answer. To the extent that an answer is required, Plaintiffs deny the allegations set forth in the “WHEREFORE” paragraph following Paragraph 66 of Mylan Pharmaceuticals’s amended counterclaims, including sub-paragraphs (a)-(g), and deny that Mylan Pharmaceuticals is entitled to any of the relief requested therein or to any relief whatsoever.

Plaintiffs further deny any allegations in Mylan Pharmaceuticals’s amended counterclaims that were not specifically admitted, denied, or answered herein.

WHEREFORE, Plaintiffs respectfully request the following relief:

- a) An order dismissing Mylan Pharmaceuticals’s amended counterclaims with prejudice;
- b) An order granting each and every prayer for relief sought by Plaintiffs in their Second Amended Complaint for Patent Infringement;
- c) An award of costs and expenses to Plaintiffs for defending against these amended counterclaims;
- d) Such further and additional relief as this Court deems just and proper.

Dated: March 2, 2015

Respectfully submitted,

/s/ Chad L. Taylor

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and Emory University*

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CERTIFICATE OF SERVICE

I hereby certify that on March 2, 2015, the foregoing **PLAINTIFFS' ANSWER TO DEFENDANT MYLAN PHARMACEUTICALS INC.'S AMENDED COUNTERCLAIMS** was served upon the attorneys of record for Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. using the CM/ECF system, which will send notification of the filing to the counsel of record for Mylan Inc. and Mylan Pharmaceuticals Inc.

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